inches which was subdivided into 2½ inch by 7 inch rectangular compartments. Each compartment was filled with a blue-colored liquid.

CHARGE: 502 (a)—the labeling of the devices, when shipped, contained false and misleading representations that the *Hot-R-Cold Mask* provided an adequate and effective treatment for sinus conditions and that the *Hot-R-Cold Pak* provided an adequate and effective treatment for stiff joints, earaches, sore throat, and swellings.

DISPOSITION: 6–15–56. Default—articles delivered to the Food and Drug Administration.

**5220. Ear stopples.** (F. D. C. No. 39289. S. No. 47–149 M.)

QUANTITY: 1 case of 100 12-tube ctns. and 1 case of 150 12-tube ctns. at Philadelphia, Pa.

SHIPPED: 5–24–56, from Los Angeles, Calif., by Healthways of Hollywood.

LABEL IN PART: (Ctn.) "Healthways The Ideal Ear Stopple Protects your ears from Water & Noise. * * * Recommended by Swim Coaches & Medical Authorities to help prevent Ear Disorders & Polio"; (tube) "Health-ways The Ideal Ear Stopple Moisten * * * Small."

RESULTS OF INVESTIGATION: The device consisted of 2 rubber stoppers designed so as to fit easily into each ear.

LIBELED: 7–2–56, E. Dist. Pa.

CHARGE: 502 (a)—the label of the article, when shipped, contained false and misleading representations that the device was effective for preventing ear disorders and polio.

DISPOSITION: 7–5–56. Consent— claimed by Healthways, Inc., and relabeled.

## INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 5201 TO 5220

### PRODUCTS



[1] (5215) Seizure contested.
[2] (5202) Injunction issued. Contains orders of the court.
[3] (5212) Seizure contested. Contains opinions of the court and instructions to the jury.

# U. S. Department of Health, Education, and Welfare

## FOOD AND DRUG ADMINISTRATION

# NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

**5221–5240**

## DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They relate to drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent and (2) criminal proceedings which were terminated with a plea of guilty or nolo contendere. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*
WASHINGTON, D. C., *August 22, 1958.*

CONTENTS*



*For omission of, or unsatisfactory, ingredients statements, see No. 5226; failure to bear a label containing an accurate statement of the quantity of the contents, No. 5226; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 5226.

***SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 5221–5240***

*Adulteration*, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, or its quality fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess.

*Misbranding*, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling; Section 502 (l), the article purported to be and was represented as a drug composed wholly or partly of chlortetracycline or a derivative thereof, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*New-drug violation*, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

## DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

**5221. Methyltestosterone tablets and Vita–40 tablets.** (F. D. C. No. 38514. S. Nos. 39–578 L, 40–262 L, 74–711 L, 11–082 M.)

INDICTMENT RETURNED: 4–4–56, S. Dist. Calif., against Vita Pharmacals, Inc., Los Angeles, Calif., and Floyd L. Clemens, president.

ALLEGED VIOLATION: The indictment alleged that a quantity of methyltestosterone had been shipped on or about 8–19–54 from New York to California, where it was fabricated into tablets and delivered to the defendants; that following such delivery and while such methyltestosterone in tablet form was being held for sale after shipment in interstate commerce, the defendants caused a quantity of the article in tablet form to be dispensed on 9–18–54 in a box without a prescription and an additional quantity of the article in tablet form to be repacked into boxes and accompanied by certain labeling in the period of 9–15–54 to 9–22–54; that the defendants' act of causing the dispensing of a quantity of the article in tablet form was an act done contrary to the provisions of 503 (b) (1), which resulted in the article being misbranded while